

Evaluation of Diabetic Retinopathy and Diabetic Macular Oedema in Early Type 2 Diabetes Mellitus: A Cross-Sectional Study

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Abstract:

Background: Diabetic retinopathy (DR) and diabetic macular oedema (DME) are important microvascular complications of type 2 diabetes mellitus (T2DM) and may occur even during the early years of disease.

Aim: To evaluate the prevalence and severity of DR and DME in patients with early T2DM and assess their association with diabetes duration and glycaemic control.

Methodology: A hospital-based cross-sectional observational study was conducted among 80 patients with T2DM of ≤ 5 years' duration at the Department of Ophthalmology, Netaji Subhas Medical College and Hospital, Bihta, Patna. Participants underwent visual acuity assessment, dilated fundus examination, retinal photography, and macular evaluation with optical coherence tomography where indicated. Clinical and biochemical parameters, including HbA1c, were recorded and analysed using SPSS version 27.0.

Results: DR was present in 29 (36.3%) participants, including mild NPDR in 18 (22.5%), moderate/severe NPDR in 8 (10.0%), and PDR in 3 (3.8%). DME was detected in 13 (16.2%) participants. DR increased from 10.7% in diabetes duration < 1 year to 76.0% in 3–5 years and from 13.3% with HbA1c $< 7\%$ to 100% with HbA1c $\geq 9\%$.

Conclusion: Retinal complications were relatively common in early T2DM and were associated with longer diabetes duration and poorer glycaemic control. Early ophthalmic screening and adequate glycaemic control are essential.

Keywords: Type 2 diabetes mellitus, diabetic retinopathy, diabetic macular oedema, HbA1c, retinal screening, optical coherence tomography.

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Introduction

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disease associated with chronic hyper-glycaemia that is caused by insulin resistance, gradual deterioration of the pancreatic β -cell function and/or both these factors. It has grown significantly in prevalence throughout the world, causing a significant burden of microvascular and macrovascular complications [1]. Diabetic retinopathy (DR) is one of the most significant microvascular complications responsible for the most preventable loss of visual function among adults. Hyperglycaemia is related to the development of DR, although retinal changes can occur during early T2DM. Thus, early detection of the presence of retinal abnormalities after the diagnosis of diabetes is crucial for the prevention of progression and maintenance of vision [2].

Diabetic retinopathy is a progressive microvascular retinal disease that is due to chronic metabolic and vascular changes of diabetes [3]. Chronic hyperglycaemia is responsible for advanced glycation end-products, inflammation, endothelial dysfunction,

loss of pericytes and leakage of the blood-retinal barrier. These pathological changes lead to leakage of the capillaries of the retina, microaneurysms, haemorrhage, ischaemia of the retina and in advanced disease, abnormal vascular proliferation. DR can generally be divided into non-proliferative diabetic retinopathy (NPDR) or proliferative diabetic retinopathy (PDR). In NPDR, microaneurysms, retinal haemorrhages, hard exudates, cotton-wool spots, and vascular abnormalities are noted while in PDR, retinal ischaemia and pathological neovascularization occur [4]. In general, the more a person has had diabetes and the poorer their control over it, the more severe their DR will become.

Retinal changes have been known to occur at or early in the diagnosis of T2DM, although DR has been traditionally described as a complication of longterm diabetes [5]. This could be due to the fact that T2DM may not be clinically diagnosed for many years. This means that the length of hyperglycaemic exposure could be much longer than is

documented. Research has shown that some have already suffered some harm to the retina's microvasculature at the point of diagnosis of T2DM. This is especially true in patients presenting with apparently early diabetes, as retinal disease is likely to be asymptomatic until there is significant structural or functional damage.

Another important diabetic retinopathy complication is diabetic macular oedema (DME), which is the leading cause of vision loss in DR patients [6]. DME is caused by a disruption of the blood-retinal barrier which causes increased vascular permeability and fluid to build up in or under the macula. This is mediated by hyperglycaemia-induced inflammation, upregulation of vascular endothelial growth factor (VEGF) and endothelial dysfunction, as well as loss of tight junctions. DME can happen at any point in the course of diabetic retinopathy and can have a dramatic impact if it involves the macula, especially when it impairs central vision. Importantly, macular oedema can occur despite having what is considered a relatively mild degree of retinopathy, which is why assessment of the macular region is necessary.

Today, thanks to the advent of modern retinal imaging techniques, the clinical assessment of DR has greatly changed. Fundus examination and fundus photography are important for the detection and grading of DR and optical coherence tomography (OCT) can give detailed cross-sectional views of the retinal layers, and quantitative measurements of retinal thickness and intraretinal or subretinal fluid [7]. In recent years, OCT has proved to be a useful tool for the detection of DME, including small changes in the macula that are not easily observed during standard eye examinations. Therefore, clinical examination of the retina is best combined with the use of suitable imaging to detect and characterise early diabetic retinal changes.

There are several systemic and metabolic factors that affect the progression and formation of DR and DME. There is a relation between higher levels of retinal risk and glycaemic control, diabetes duration, hypertension, dyslipidaemia, renal dysfunction, obesity and other metabolic abnormalities [8]. Glycated haemoglobin (HbA1c) is especially significant because it correlates with average glucose levels over the past few months and has been shown to be a key link to the development and progression of diabetic microvascular complications. Evaluation of such systemic factors, in addition to assessment of ocular findings, can help to better understand the retinal involvement of patients with T2DM.

Early detection of DR and DME is particularly crucial, since some early signs of DR may not produce symptoms and could be treated through timely intervention and control of systemic risk factors. Routine eye exams allow identification of individuals who need more detailed eye care. Good management of

hyperglycaemia, blood pressure, lipid abnormalities and other modifiable risk factors decreases the risk of progression of DM microvascular complications [9]. For those who have clinically significant DME or advanced retinopathy, timely ophthalmic treatments can help lower the risk of irreversible vision loss.

Although screening and retinal imaging are improving in patients with early T2DM, the burden of retinal abnormalities within this population may differ based on population characteristics, access to health care, metabolic control and duration of undiagnosed diabetes. Local assessment for DR and DME in persons with more recent T2DM is therefore of significance in determining the frequency and pattern of DR and DME in such subjects. A cross sectional assessment can give information about the presence and severity of changes to the retina, and how these are associated to the relevant clinical and biochemical parameters.

The aim of the present study titled "Evaluation of Diabetic Retinopathy and Diabetic Macular Oedema in Early Type 2 Diabetes Mellitus: A Cross-Sectional Study" was to evaluate the retinal involvement in early T2DM. To identify diabetic retinopathy and diabetic macular oedema by proper ophthalmic examination and retinal imaging, the study concentrates on these issues. It also seeks to offer an insight into the connection between early retinal abnormalities and associated demographic, clinical and metabolic profile. This assessment could serve to highlight the significance of early screening for T2DM and enable early detection of those who may be at risk of diabetic retinal complications that can lead to vision loss.

Methodology

Study Design: A hospital-based cross-sectional observational study was conducted to evaluate the presence and severity of diabetic retinopathy (DR) and diabetic macular oedema (DME) among patients with early type 2 diabetes mellitus (T2DM). The study assessed demographic characteristics, duration of diabetes, glycaemic status, visual acuity, retinal findings, and other relevant clinical parameters at a single point of evaluation.

Study Area: The study was conducted in the Department of Ophthalmology, Netaji Subhas Medical College and Hospital, Bihta, Patna, Bihar, India.

Study Duration: The study was conducted over a period of one year from January 2024 to December 2024.

Study Participants

Inclusion Criteria

- Patients aged 18–70 years.

- Patients with a confirmed diagnosis of type 2 diabetes mellitus.
- Patients with diabetes duration of ≤ 5 years.
- Patients who provided written informed consent for participation.
- Patients who were able to undergo visual acuity assessment and ophthalmic examination.
- Patients who were willing to undergo retinal photography and other required investigations.

Exclusion Criteria

- Patients with type 1 diabetes mellitus or other specific types of diabetes.
- Patients with diabetes duration of more than 5 years.
- Patients with previously diagnosed retinal diseases unrelated to diabetes.
- Patients with significant media opacity preventing adequate retinal examination.
- Patients with previous retinal laser treatment, intravitreal injection, or vitreoretinal surgery.
- Patients with severe systemic illness requiring immediate hospitalisation.
- Pregnant women were excluded from the study.
- Patients who did not provide informed consent or were unable to complete the required examination.

Sample Size: The sample size consisted of 80 patients with early type 2 diabetes mellitus who fulfilled the predefined inclusion and exclusion criteria. Consecutive eligible participants attending the Department of Ophthalmology during the study period were recruited until the required sample size was achieved.

Procedure: After obtaining written informed consent, each participant underwent a standardized clinical and ophthalmological assessment. Demographic details, history of diabetes, duration of diabetes, history of hypertension, medication use, and relevant systemic conditions were recorded using a structured data collection form. Anthropometric measurements, including weight and height, were recorded, and body mass index was calculated as weight in kilograms divided by height in metres squared. Blood pressure was measured in the seated position. Relevant laboratory investigations, including fasting blood glucose and glycated haemoglobin (HbA1c), were recorded or performed according to institutional protocols.

Visual acuity was assessed separately for each eye using a standardized visual acuity chart, and pinhole correction was performed where required. Anterior segment examination was carried out using a slit lamp. Fundus evaluation was performed after appropriate pupillary dilatation when required. Digital retinal photographs were obtained using a fundus

camera, with images centred on the optic disc and macular regions. If the retinal photographs were inadequate because of poor visualization, pharmacological pupillary dilatation was performed before repeat imaging. The retinal photographs were evaluated systematically for microaneurysms, retinal haemorrhages, hard exudates, cotton-wool spots, venous abnormalities, neovascularization, and other features of diabetic retinopathy. DR was classified according to the severity of retinal lesions into no retinopathy, mild/non-proliferative retinopathy, moderate or severe non-proliferative retinopathy, and proliferative retinopathy. The macular area was specifically examined for evidence of diabetic macular oedema, including retinal thickening and associated exudative changes. Optical coherence tomography, where clinically indicated and available, was used to further assess macular involvement and retinal thickness. The final diagnosis was based on the ophthalmic examination and retinal imaging findings, with the worse eye considered for patient-level classification.

Statistical Analysis: The collected data were entered, coded, and analysed using IBM SPSS Statistics version 27.0. Continuous variables were expressed as mean $\pm$ standard deviation or median with interquartile range, while categorical variables were presented as frequencies and percentages. The Chi-square test or Fisher's exact test was used for comparison of categorical variables, while the independent Student's t-test or Mann-Whitney U test was used for comparison of continuous variables, as appropriate. Associations between diabetic retinopathy, diabetic macular oedema, and relevant clinical variables were assessed using appropriate statistical tests. A p-value <0.05 was considered statistically significant.

Result

Table 1 presents the demographic characteristics of the 80 study participants according to age and sex. The largest proportion of participants belonged to the 31–40 years age group, comprising 24 (30.0%) participants, followed by the 41–50 years group with 22 (27.5%) participants. The 18–30 years age group included 18 (22.5%) participants, while 16 (20.0%) participants were aged 51–70 years. Thus, participants aged 31–50 years constituted the majority of the study population. Regarding sex distribution, males predominated, accounting for 46 (57.5%) participants, whereas females comprised 34 (42.5%). Overall, the study population demonstrated a relatively balanced representation of both sexes, although males were more frequently represented. The findings indicate that the study participants were predominantly middle-aged adults, with the highest proportion falling within the 31–40 years age group.

Table 1: Demographic characteristics of the study participants (N=80)

Variable	Category	Frequency (n)	Percentage (%)
Age (years)	18–30	18	22.5
	31–40	24	30
	41–50	22	27.5
	51–70	16	20
Sex	Male	46	57.5
	Female	34	42.5
Total		80	100

Table 2 presents the clinical characteristics and duration of diabetes among the 80 study participants. The majority of participants had diabetes for less than 1 year, accounting for 28 (35.0%) patients, followed by those with a duration of 1–2 years comprising 27 (33.8%) participants. A total of 25 (31.2%) participants had diabetes for 3–5 years, indicating a relatively balanced distribution across the duration categories. Hypertension was present in 22 (27.5%) participants, whereas 58 (72.5%)

participants did not have hypertension. Regarding glycemic control, 30 (37.5%) participants had an HbA1c level <7%, while the largest proportion, 36 (45.0%), had HbA1c levels between 7–8.9%. Furthermore, 14 (17.5%) participants had HbA1c levels ≥9%. Overall, the findings indicate that most participants had a relatively recent diagnosis of diabetes, while nearly two-thirds had HbA1c levels ≥7%, suggesting suboptimal glycemic control in a substantial proportion of the study population.

Table 2: Clinical characteristics and duration of diabetes among study participants (N=80)

Variable	Category	Frequency (n)	Percentage (%)
Duration of diabetes	<1 year	28	35
	1–2 years	27	33.8
	3–5 years	25	31.2
Hypertension	Present	22	27.5
	Absent	58	72.5
HbA1c	<7%	30	37.5
	7–8.9%	36	45
	≥9%	14	17.5
Total		80	100

Table 3 presents the distribution of diabetic retinopathy according to severity among the 80 study participants. The majority of participants, 51 (63.7%), had no evidence of diabetic retinopathy. Mild non-proliferative diabetic retinopathy was observed in 18 (22.5%) participants, making it the most common form among those with retinopathy. Moderate/severe non-proliferative diabetic retinopathy was present in 8 (10.0%) participants, while proliferative diabetic retinopathy was identified in 3

(3.8%) participants. Thus, diabetic retinopathy of any severity was present in 29 (36.3%) participants, whereas 51 (63.7%) had no retinopathy. Overall, the findings indicate that although the majority of participants were free from diabetic retinopathy, more than one-third had some degree of retinal involvement. Among affected participants, non-proliferative forms predominated, while proliferative diabetic retinopathy was comparatively uncommon.”

Table 3: Distribution of diabetic retinopathy according to severity (N=80)

Diabetic retinopathy status	Frequency (n)	Percentage (%)
No diabetic retinopathy	51	63.7
Mild non-proliferative diabetic retinopathy	18	22.5
Moderate/severe non-proliferative diabetic retinopathy	8	10
Proliferative diabetic retinopathy	3	3.8
Total	80	100

“Table 4 presents the distribution of diabetic macular oedema among the 80 study participants. The majority of participants, 67 (83.8%), had no evidence of diabetic macular oedema. Mild or early macular oedema was observed in 8 (10.0%) participants, while clinically significant macular oedema was identified in 5 (6.2%) participants. Overall,

diabetic macular oedema of any degree was present in 13 (16.2%) participants. Thus, the findings indicate that macular oedema was relatively less common than the absence of oedema in the study population. Among participants with diabetic macular oedema, mild or early disease constituted the larger proportion compared with clinically significant

macular oedema. These findings demonstrate that although most participants did not have macular oedema, a notable proportion had some degree of

macular involvement, emphasizing the presence of ocular complications even in the studied population with relatively early type 2 diabetes mellitus.

Table 4: Distribution of diabetic macular oedema among study participants (N=80)

Diabetic macular oedema status	Frequency (n)	Percentage (%)
No diabetic macular oedema	67	83.8
Mild/early macular oedema	8	10
Clinically significant macular oedema	5	6.2
Total	80	100

Table 5 presents the association of diabetic retinopathy (DR) with duration of diabetes and HbA1c among 80 participants. The proportion of participants with DR increased markedly with longer diabetes duration, from 3 (10.7%) among those with diabetes for <1 year to 7 (25.9%) among those with 1–2 years of duration and 19 (76.0%) among those with 3–5 years of duration. A similar pattern was observed with increasing HbA1c levels. DR was present in 4 (13.3%) participants with HbA1c <7%,

compared with 11 (30.6%) among those with HbA1c 7–8.9% and all 14 (100.0%) participants with HbA1c $\geq 9\%$. Conversely, the proportion without DR decreased with increasing diabetes duration and HbA1c. These findings demonstrated a clear descriptive association of DR with longer duration of diabetes and poorer glycaemic control, with the highest proportion of DR observed among participants having diabetes for 3–5 years and HbA1c $\geq 9\%$.

Table 5: Association of diabetic retinopathy with duration of diabetes and HbA1c (N=80)

Clinical variable	Category	DR present n (%)	DR absent n (%)	Total
Duration of diabetes	<1 year	3 (10.7)	25 (89.3)	28
	1–2 years	7 (25.9)	20 (74.1)	27
	3–5 years	19 (76.0)	6 (24.0)	25
HbA1c	<7%	4 (13.3)	26 (86.7)	30
	7–8.9%	11 (30.6)	25 (69.4)	36
	$\geq 9\%$	14 (100.0)	0 (0.0)	14

Discussion

This cross-sectional study examined the prevalence of diabetic retinopathy (DR) and diabetic macular oedema (DME) in 80 patients with relatively early type 2 diabetes mellitus (T2DM) with a focus on the association of retinal complications with diabetes duration and glycaemic control. The prevalence of DR in this study population was 36.3% and the prevalence of no DR was 63.7%. Mild NPDR (grade) was the most common (22.5%), followed by moderate/severe NPDR (10.0%) and PDR (3.8%). The relatively high prevalence of DR despite having had diabetes for only 5 years or less indicates that microvascular changes in DR might occur early in type 2 diabetes.”

“The prevalence seen in the current study was higher than that of Lee and Sum 2011 [10] who conducted a study and found DR cases among patients with recently diagnosed diabetes mellitus in 18.2%. In a large Swedish cohort of recently diagnosed patients (Martinell et al. 2016 [11]), DR was found in 12% of the patients, including 7% with mild and 5% with moderate DR. The percentage of these values is much lower compared to 36.3% that was obtained in the current study. The current result was more similar to the pooled value of the global prevalence estimated by Yau et al. (2012) [12] which was 34.6% of

22,896 people with diabetes. Some studies compared with the present study may have included patients at or very close to the time of diagnosis, which could account for some of the differences between the two studies.

The results also illustrated a definite preponderance of early-stage disease. Twenty-two point five per cent (22.5%) had mild NPDR and only 3.8 per cent had PDR in the present study. This is similar to the findings of Martinell et al. (2016) who documented 7% mild and 5% moderate DR at diagnosis, and no advanced proliferative disease. The low percentage of PDR in the current study may suggest that while vascular injury can be early and precede advanced PDR, PDR in most cases will require longer exposure to metabolic abnormalities. Yau et al. (2012) also found that the prevalence of DR rose significantly with the duration of diabetes, ranging from 21.1% with diabetes for less than 10 years to 76.3% with diabetes for 20 years or more.

An interesting finding in the present study was that the proportion of people with DR was related to the duration of diabetes, with 10.7% of diabetics having no DR, 25.9% having DR for 1–2 years and 76.0% having DR for 3–5 years. This incremental rise is corroborated by the study performed by Chennai Urban Rural Epidemiology Study by Pradeepa and his

colleagues, 2010 [13] which found DR in 17.5% of 1,608 South Indian patients of Type 2 Diabetes. Important risk factors for microvascular complications identified were age, HbA1c and diabetes duration. These findings were also seen in the previous CURES data, where they found that the risk of developing DR was 1.89 times greater for every 5 years of diabetes. In addition, Jin et al., 2014 [14] performed a five-year prospective study of 778 Chinese type 2 diabetics, and observed an incidence rate of 46.89%, with hyperglycaemia and high blood pressure at baseline being independent risk factors for the development of DR. The present study's results corroborate the pattern seen in these findings, even though the study was cross-sectional and does not allow for making temporal inferences.

The correlation was even stronger between glycaemic control and DR. In the present study, DR was present in 13.3% of participants with HbA1c <7%, 30.6% with HbA1c 7–8.9%, and 100% of those with HbA1c ≥9%. As a result, there was a progressive increase in the frequency of DR with worsening glycaemic control. This finding is corroborated by Yau et al. (2012) [15] who found DR prevalence was 18.0% in people with HbA1c levels ≤7.0%, and 51.2% in those with HbA1c >9.0%. Cheng et al. (2009) [16] also, using NHANES data from 1,066 people, showed a clear rise in prevalence of retinopathy with increasing HbA1c, and reported that HbA1c was a better discriminator of retinopathy than fasting plasma glucose. This 14 patients' 100% DR prevalence in those with HbA1c ≥9% in the current study is consistent with the overall data supporting the association between chronic hyperglycaemia and retinal microvascular injury.

16.2% of the present participants had DME, of which 10.0% had mild/early DME and 6.2% had clinically significant macular oedema. This prevalence was also higher than pooled prevalence of 6.81% in the global literature reported by Yau et al. (2012) and approximately 5.47% pooled prevalence reported in a 2022 systematic review and meta-analysis using OCT. It was however, reasonably comparable to that reported by Martinell et al. (2016) among recently diagnosed patients which was 11% DME. These differences could be due to patient selection, length of time a patient has had diabetes, imaging technique and definition of DME. The lower rate of DME incidence in the current study compared to DR is clinically anticipated because that DME is just one of the clinical signs of DR and not all retinopathy cases are necessarily DME. Tan et al. (2017) [17] pointed out that DME is closely associated with retinal vascular leakage, metabolic abnormalities, and that it is still an important cause of diabetes-related visual impairment.

There were 27.5% of the current participants with hypertension. While the current analysis showed associations of DR with diabetes duration and HbA1c,

it is clinically important that the majority of the population (over 1/4) had hypertension since blood pressure has consistently been associated with DR. Yau et al. (2012) have reported that the prevalence of DR has been found to be higher with higher blood pressure and Jin et al. (2014) have found high blood pressure to be an independent risk factor for DR onset. In general, the present results corroborate the fact that retinal abnormalities can develop within the first several years of a diagnosis of type 2 diabetes, especially in the event of substandard glycaemic control. Early ophthalmic evaluation, timely monitoring of HbA1c, and blood pressure and frequent retinal examinations might thus help prevent the development of DME and DR to more serious stages that can lead to vision loss. The present study was cross-sectional, and the findings are for the 80 subjects that were studied; thus, the observed associations are not necessarily causal."

Conclusion

The present cross-sectional study demonstrated that diabetic retinal abnormalities were relatively common even among patients with early type 2 diabetes mellitus. Diabetic retinopathy was detected in 36.3% of participants, with mild non-proliferative retinopathy being the predominant form, while proliferative disease was less frequent. Diabetic macular oedema was identified in 16.2% of participants, indicating clinically relevant macular involvement during the early diabetic period. A marked increase in retinopathy was observed with longer diabetes duration and increasing HbA1c levels, with the highest prevalence among patients with diabetes for 3–5 years and HbA1c ≥9%. These findings emphasize the importance of early ophthalmic screening, adequate glycaemic control, and regular retinal monitoring in patients with type 2 diabetes mellitus to facilitate timely detection and management of retinal complications.

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